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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,581	04/15/2004	John A. Salon	57453-AA-PCT-US/JPW/MJW	8876

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EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
05/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,581	SALON ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *169-180* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *169-180* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/17/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 169-180 are pending in the instant application. Claims 1-168 have been canceled as requested by Applicant in the preliminary amendment filed April 15, 2004.

All claims are currently under examination.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on February 12, 2007 has been considered by the examiner.

Advisory Information

3. In the previous office action claim 180 had been objected to as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 180 had been drawn to a nonneuronal cell, but it was dependent on claim 177, which is drawn to an insect cell.

In the amendment submitted February 12, 2007, Applicants corrected the dependency so that claim 180 now depends from claim 179, but the amended claim was labeled "previously entered".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4.1 Claims 169-180 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,221,616. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a process for determining whether a chemical compound is a human melanin concentrating hormone receptor antagonist which comprises

contacting cells transfected with and expressing DNA encoding the human MCH 1 receptor with the compound in the presence of a known human MCH1 receptor agonist, and contacting cells separately with only the agonist, under conditions permitting the activation of the human MCH 1 receptor, and detecting a decrease in human MCH1 receptor activity compared to cells contacted only with the agonist, so as to thereby determine whether the compound is a human MCH1 receptor antagonist; wherein the human MCH1 receptor is encoded by an isolated nucleic acid having consecutive nucleotides having 1)the sequence beginning with the start codon at positions 1-3, and ending at the stop codon at positions 1267-1269 as indicated in Figure 1 (SEQ ID NO: 1) or 2) the sequence beginning with the start codon at positions 16-18, and ending at the stop

positions 1267-1269 as indicated in Figure 1 (SEQ ID NO: 1) and which

wherein the human MCH 1 receptor is activated by melanin concentrating hormone, whereas the claims of U.S. Patent No. 6,221,616 are drawn to A process for determining whether a chemical compound is a human Melanin-concentrating hormone 1 (MCH1) receptor antagonist which comprises contacting cells transfected with and expressing DNA encoding the human MCH1 receptor with the compound in the presence of a known human MCH1 receptor agonist, under conditions permitting the activation of the human MCH1 receptor, and detecting human MCH1 receptor activity, wherein a decrease in human MCH1 receptor activity in the presence of both the compound and the known agonist relative to the activity of the human MCH1 receptor in the presence of the known agonist alone indicates that the compound is a human MCH1 receptor antagonist, wherein the DNA encoding the human MCH1 receptor comprises the sequence shown in FIG. 1 (SEQ ID NO: 1) or contained in plasmid pEXJ.HR-TL231 (ATCC Accession No. 203197), the known human MCH1 receptor agonist is Melanin-concentrating hormone (MCH) or an analog of MCH, and the cells do not express the MCH1 receptor prior to transfecting them. Therefore, the claims differ slightly in scope by having the cells of the patent expression the MCHR contained in plasmid pEXJ.HR-TL231.

4.2 Claims 169-180 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,291,195. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a process for determining whether a chemical compound is a human melanin concentrating hormone receptor antagonist, and the claims of U.S. Patent No. 6,291,195 are drawn to a process for preparing a composition which comprises identifying a compound that

binds to a human MCH1 receptor encoded by SEQ ID NO: 1 or encoded by plasmid pEXJ.HR-TL231, comprising admixing a carrier. Therefore, the claims differ in scope by having the cells of the patent expression the MCHR contained in plasmid pEXJ.HR-TL231 and by admixing a carrier to the identified compound.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 169-180 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for determining whether a chemical compound is a human MCH1 receptor antagonist in which the method uses a MCH1 receptor agonist. Thus, the claims are drawn to a genus of compounds in which there is no specific structure, but only an activity. The specification and the art teaches that MCH (melanin concentrating hormone) is the agonist for the MCH1 receptor. However, there are no other compounds taught in the specification or the art that are agonists for MCH1 receptor. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics,

structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, there is only a functional characteristic necessary. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only MCH as the agonist, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-*

Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Conclusion

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nichol can be reached at (571) 272-0835.

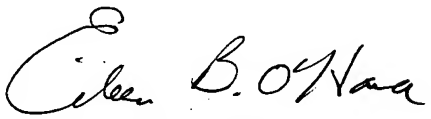
The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner



EILEEN B. O'HARA
PRIMARY EXAMINER